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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,423	11/26/2003	Gerard M. Jensen	1992.005US1	6232

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/723,423	Applicant(s) JENSEN ET AL.	
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11-2-04; 1-10-05</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims included in the prosecution are 1-38.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing. It recites two functional limitations 1 and 2, which contradict each other in terms of half-life. The same is the case with the other independent claims.

Phosphatidylcholine is a single compound. Therefore, it is unclear as to what applicant intends to convey by one or more phosphatidylcholine in claim 2.

Claims 18-20 recite specific ratios of the lipid and therapeutic agent with an additional limitation of 'greater than'. This expression is confusing. Which is greater, the lipid or the therapeutic agent?

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-13, 15-23, 25, 27, 30-34 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Lopez-Berestein (5,032,404).

Lopez-Berestein discloses liposomes containing polyene antibiotics which include amikacin. The liposomal formulations contain various claimed phospholipids and cholesterol. The liposomes are either unilamellar or multilamellar. The liposomes are administered parenterally. The lipid-drug ratios and the lipid-cholesterol ratios disclosed by Lopez-Berestein fall within the claimed ratios (abstract; col. 8, lines 34-66; col. 9, lines 15-47; Examples, in particular Example 3, 15 and claims). Instant claims contain the functional limitation of half-life. The burden is upon applicant that the formulations of prior art do not meet this limitation since it discloses the same formulation.

5. Claims 1-11, 13-24, 28, 30-34 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Hersch (5,759,571).

Hersch discloses liposomes containing amino glycoside, amikacin. The liposomal formulations contain various claimed neutral phospholipids DMPC, DSPC, DPPC, anionic phospholipids and cholesterol, in particular HSPC and DSPG and cholesterol in claimed ratios. The lipid-drug ratios fall within the claimed amounts. The liposomal sizes are less than 100 nm. The method disclosed includes IV injection into mice. The method also includes patients (humans) (abstract; col. 3, line 65 through col. 6, line 63; Examples and claims). Instant claims contain the functional limitation of half-life. The burden is upon applicant that the formulations of prior art do not meet this limitation since it discloses the same formulation.

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6. Claims 1-11, 13, 15-23, 31-35 and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Newman (Cancer Chemother Pharmacol., 1999) of record.

Newman discloses the effectiveness of cisplatin encapsulated liposomal formulation. The liposomes contain HSPC and cholesterol in claimed amounts. The drug to lipid ratio of 0.014 (abstract; Materials and Methods and Results). Instant claims contain the functional limitation of half-life. The burden is upon applicant that the formulations of prior art do not meet this limitation since it discloses the same formulation.

7. Claims 1-24, 29-35 and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Abra (5,945,122).

Abra discloses liposomal formulations containing cisplatin, HSPC, cholesterol and DSPG in instant ratios. The amounts of lipid and drug and the sizes of the liposomes fall within the claimed amounts (abstract, col. 9, line 26 through col. 10, line 12; col. 11, lines 25-36, col. 13, lines 36-51; Examples, example 5 in particular and claims). Instant claims contain the functional limitation of half-life. The burden is upon applicant that the formulations of prior art do not meet this limitation since it discloses the same formulation.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4--8, 14, 18-20, 24-30 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lopez-Berestein cited above.

The teachings of Lopez-Berestein have been discussed above. Lopez-Berestein does not teach all of the claimed ratios with respect to the phospholipids and cholesterol and the lipid and the drug. However, in the absence of showing unexpected results, it is deemed obvious to one of ordinary skill in the art to vary the amounts of the lipids, cholesterol and drug from the guidance provided by Hersch to obtain the best possible results. Although Lopez-Berestein teaches the use of unilamellar and multilamellar liposomes, he does not specifically state the sizes of the unilamellar vesicles. However, since unilamellar liposomes are of smaller sizes, it is deemed to be within the skill of the art to prepare liposomes of smaller sizes if desired, with a reasonable expectation of success. Lopez-Berestein does not teach the encapsulation of anti-cancer drugs such as cisplatin. However, the principle of encapsulation is the same, one of ordinary skill in the art would be motivated to encapsulate cisplatin if the desired goal is to treat cancer.

10. Claims 4-8, 18-20, 24-30 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hersch cited above.

The teachings of Hersch have been discussed above. Hersch does not teach all of the claimed ratios with respect to the phospholipids and cholesterol and the lipid and the drug. However, in the absence of showing unexpected results, it is deemed obvious

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to one of ordinary skill in the art to vary the amounts of the lipids, cholesterol and drug from the guidance provided by Hersch to obtain the best possible results. Hersch also does not teach the encapsulation of anti-cancer drugs such as cisplatin. However, the principle of encapsulation is the same, one of ordinary skill in the art would be motivated to encapsulate cisplatin if the desired goal is to treat cancer.

11. Claims 2-4, 6-12, 18-20, 24-30 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abra cited above.

The teachings of Abra have been discussed above. Abra does not teach all of the claimed ratios with respect to the phospholipids and cholesterol and the lipid and the drug and various phospholipids. However, in the absence of showing unexpected results, it is deemed obvious to one of ordinary skill in the art to vary the amounts of the lipids, cholesterol and drug and use art known phospholipids from the guidance provided by Hersch to obtain the best possible results.

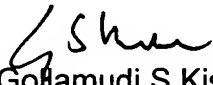
The reference of Anaissie (4,999,199) is cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK